

**ADULT LOW DOSE ASPIRIN- aspirin tablet, delayed release**  
**Rising Pharma Holdings, Inc.**

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**Compare to the active ingredient in Bayer® Low Dose Aspirin†**

**Adult Low Dose  
Aspirin  
81 mg  
Pain Reliever (NSAID)  
adult aspirin regimen use  
delayed release  
safe pain relief  
SEE NEW WARNINGS INFORMATION**

**120 Tablets**

**DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.**

***Drug Facts***

| <b><i>Active ingredient (in each tablet)</i></b> | <b><i>Purpose</i></b> |
|--|-----------------------|
| Aspirin 81 mg (NSAID)*.....                      | Pain reliever         |
| *nonsteroidal anti-inflammatory drug             |                       |

***Uses***

- temporary relief of minor aches and pains or as recommended by your doctor.  
**Because of its delayed release action, this product will not provide fast relief of headache or symptoms needing immediate relief.**

***Warnings***

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**Allergy alert:** Aspirin may cause a severe allergic reaction, which may include:

- hives
- shock
- facial swelling
- asthma (wheezing)

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding.

The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems

- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

**Do not use**

- if you are allergic to aspirin, or any other pain reliever/fever reducer

**Ask a doctor before use if**

- You have asthma
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis or kidney disease
- you are taking a diuretic

**Ask a doctor or pharmacist before use if you are**

- taking a prescription drug for diabetes, gout, or arthritis
- under a doctor's care for any serious condition
- taking any other drug

**Stop use and ask a doctor if**

- you experience any of the following signs of stomach bleeding:
  - feel faint
  - has bloody or black stools
  - vomits blood
  - has stomach pain that does not get better
- an allergic reaction occurs. Seek medical help right away.
- ringing in the ears or loss of hearing occurs
- pain gets worse or lasts for more than 10 days
- fever get worse or lasts for more than 3 days
- redness or swelling is present in the painful area
- new symptoms appear. These could be sign of a serious condition.

**If pregnant or breast-feeding,** ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even

if you do not notice any signs or symptoms.

**Directions**

- drink a full glass of water with each dose
- **adults and children 12 years and over:**
- take 4 to 8 tablets every 4 hours while symptoms last
- do not take more than 48 tablets in 24 hours unless directed by doctor
- **children under 12 years:** ask a doctor

**Other information**

- store at room temperature 15-30°C (59-86°F)

**Inactive ingredients**

Colloidal silicon dioxide, croscarmellose sodium, D&C yellow 10, iron oxide yellow 6, lactose, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, polysorbate 80, sodium hydroxide, talc, titanium dioxide, triethyl citrate

**Questions and comments? Call 1-844-474-7464**

**Distributed by:**

Rising Pharma Holdings, Inc.  
East Brunswick, NJ 08816

Made in India

Mfg. Lic. No.: G/25/1362

**Issued:** 06/2025

S-063

†This product is not manufactured or distributed by Bayer, owner of the registered trademark Aspirin Regimen BAYER®

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

**Adult Low Dose**

**Aspirin**

**81 mg**

**NDC 57237-349-12**

**120 Tablets**

Rising NDC 57237-349-12

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**81 mg**

Pain Reliever (NSAID)

- adult aspirin regimen use
- delayed release
- safe pain relief

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- hives ■ shock ■ facial swelling ■ asthma (wheezing)
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**Do not use** ■ if you are allergic to aspirin, or any other pain reliever/fever reducer

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OPEN FOR FULL LABELING

### Drug Facts (continue)

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### Stop use and ask a doctor if

■ you experience any of the following signs of stomach bleeding: ■ feel faint ■ has bloody or black stools ■ vomits blood ■ has stomach pain that does not get better ■ an allergic reaction occurs. Seek medical help right away.

■ ringing in the ears or loss of hearing occurs ■ pain gets worse or lasts for more than 10 days ■ fever get worse or lasts for more than 3 days ■ redness or swelling is present in the painful area ■ new symptoms appear. These could be sign of a serious condition.

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**Inactive ingredients:** Colloidal silicon dioxide, croscarmellose sodium, D&C yellow 10, iron oxide yellow 6, lactose, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, polysorbate 80, sodium hydroxide, talc, titanium dioxide, triethyl citrate

**Questions and comments?** Call 1-844-474-7464

## ADULT LOW DOSE ASPIRIN

aspirin tablet, delayed release

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:57237-349 |
| <b>Route of Administration</b> | ORAL           |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength |
|---|-------------------|----------|
| ASPIRIN (UNII: R16CO5Y76E) (ACETYLSALICYLIC ACID - UNII:R16CO5Y76E) | ASPIRIN           | 81 mg    |

### Inactive Ingredients

| Ingredient Name                         | Strength |
|---|----------|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)      |          |
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) |          |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)    |          |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT)  |          |

|   |  |
|---|--|
| <b>LACTOSE, UNSPECIFIED FORM</b> (UNII: J2B2A4N98G)                     |  |
| <b>METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER</b> (UNII: NX76LV5T8J) |  |
| <b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)                    |  |
| <b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)                                |  |
| <b>sodium hydroxide</b> (UNII: 55X04QC32I)                              |  |
| <b>TALC</b> (UNII: 7SEV7J4R1U)  |  |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                              |  |
| <b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)                              |  |

### Product Characteristics

|                 |        |                     |          |
|-----------------|--------|---------------------|----------|
| <b>Color</b>    | yellow | <b>Score</b>        | no score |
| <b>Shape</b>    | ROUND  | <b>Size</b>         | 7mm      |
| <b>Flavor</b>   |        | <b>Imprint Code</b> | 81       |
| <b>Contains</b> |        |                     |          |

### Packaging

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:57237-349-12 | 120 in 1 BOTTLE; Type 0: Not a Combination Product | 07/09/2025           |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M013                                     | 07/09/2025           |                    |

**Labeler** - Rising Pharma Holdings, Inc. (116880195)

**Registrant** - Elysium Pharmaceuticals Ltd (915664486)

### Establishment

| Name                        | Address | ID/FEI    | Business Operations                          |
|-----------------------------|---------|-----------|--|
| Elysium Pharmaceuticals Ltd |         | 915664486 | manufacture(57237-349) , analysis(57237-349) |

### Establishment

| Name                        | Address | ID/FEI    | Business Operations                |
|-----------------------------|---------|-----------|------------------------------------|
| Elysium Pharmaceuticals Ltd |         | 863182240 | label(57237-349) , pack(57237-349) |

Revised: 7/2025

Rising Pharma Holdings, Inc.